REMARKS

This is a response to a second communication from Examiner Davis in which a duplicative restriction requirement was somehow inadvertently mailed to Applicants' Attorney on August 3, 2006. A original restriction requirement was mailed to Applicants' Attorney on May 25, 2006 to which a response was duly and timely filed on June 14, 2006. A copy of the original response together with evidence of its receipt by the U.S.P.T.O. is included herewith.

This inadvertent duplicity of the restriction requirement was pointed out to Examiner Davis by the undersigned during an informal telephone interview on August 18, 2006. As Examiner Davis was unable to explain how or why this occurred, the undersigned was instructed to re-file the original election of June 14 in response to the subsequent restriction of August 3, 2006. This paper, as pointed out above, is attached hereto. An expeditious examination and review of the original election and electronic response to the restriction is respectfully requested. If any further questions or issues in this matter remain unresolved, the Examiner is respectfully requested to Contact the undersigned at his number so noted.

Respectfully submitted,

Craig M. Bell

Craig M. Bell
Attorney for Applicant
Registration No. 31,812

sanofi-aventis U.S. LLC
U.S. Patent Operations
Route #202-206 / P.O. Box 6800
MAIL STOP: BWD-303A
Bridgewater, NJ 08807-0800
Telephone: 908-231-2387
Telefax: 908-231-2626

bb 6/16/06

file copy

Acknowledgement Receipt

The USPTO has received your submission at **15:30:42** Eastern Time on **14-JUN-2006** .

No fees have been paid for this submission. Please remember to pay any required fees on time to prevent abandonment of your application.

eFiled Application Information

EFS ID	1077898
Application Number	10807781
Confirmation Number	4273
Title	Composition, process of making, and medical use of substituted 4-phenyltetrahydroisoquinolines
First Named Inventor	Armin Hofmeister
Customer Number or Correspondence Address	5487
Filed By	Balaram Gupta
Attorney Docket Number	DEAV2003/0025 US NP
Filing Date	24-MAR-2004
Receipt Date	14-JUN-2006
Application Type	Utility

Application Details

Submitted Files	Page Count	Document Description	File Size	Warning
DEAV20030025USNPRESPONSETORESTRICTIONREQUIREMENT.pdf	5	Response to Election / Restriction Filed	256065 bytes	PASS

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

If you need help:

- *Call the Patent Electronic Business Center at (866) 217-9197 (toll free) or e-mail EBC@uspto.gov for specific questions about Patent e-Filing.*
- *Send general questions about USPTO programs to the USPTO Contact Center (UCC) .*

PATENT

Docket No.: DEAV2003/0025 US NP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of
Armin Hofmeister, et al.

Serial No.: **10/807,781**

Filed: **March 24, 2004**

Title: **Composition, Process of Making, and Medical Use of Substituted 4-Phenyltetrahydroisoquinolines**

Examiner: Davis, Zinna Northington

Art Unit: 1625

Certificate of Transmission

I hereby certify that this correspondence is being transmitted via EFS-Web to the Commissioner for Patents, Washington, D.C. 20231, on

June 14, 2006
Date of Transmission

Brian Pritchett Brian Pritchett
Signature

Mail Stop **Amendment**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Response to Restriction/Election Requirement Under 35 U.S.C. § 121

Sir:

This is in response to the Office Action, Paper No. 0506, dated, May 25, 2006, having a response due by June 25, 2006 in the above-identified patent application. It is respectfully requested that the following provisional election, and the remarks be entered in this case.

PROVISIONAL ELECTION:

Applicants provisionally elect with traverse the invention Group I, claims 1-6, 14 and 15 drawn to a chemical compound and a pharmaceutical composition of formula I.

ELECTION OF A SUB-SPECIES AND A SINGLE DISCLOSED COMPOUND:

Applicants provisionally elect with traverse a sub-generic species falling within the scope of invention Group I to be a compound of formula I, wherein $R_1 = R_3 = R_6 = R_7 = R_8$ = hydrogen, $R_2 = R_4$ = halogen, R_5 = alkyl, R_9 = L-G, wherein L = $NR_{30}CO$-, and G = $C_a(OR_{32})_xH_{2a+1-x}$, wherein $R_{30} = R_{32}$ = hydrogen and x = a = 5. A single specific compound falling within this sub-generic species is N-[3-(6,8-dichloro-2-methyl-1,2,3,4-tetrahydroisoquinolin-4-yl)phenyl]-(2R,3S,4R,5R)-2,3,4,5,6-pentahydroxyhexanamide,

which is described as Example 2 at line 42, page 43 to line 22, page 44 of the specification. Please note that all of claims 1 to 6, 14 and 15 read on this elected subgeneric species as well as the single disclosed compound as provisionally elected herein.

Remarks

In the Office Action, the Examiner noted that claims 1 to 15 are subject to restriction. In particular, the Examiner has given a four-way restriction in accordance with 35 U.S.C. 121 as follows:

Inventions	*Classification*
Group I. Claims 1-6, 14 and 15 drawn to a chemical compound and a pharmaceutical composition of formula I.	Not provided
Group II. Claim 7 drawn to a medicament comprising a chemical compound of formula I.	Not provided
Group III. Claim 8-13 drawn to a method of treatment of various disorders using a chemical compound of formula I.	Not provided
Group IV. Claim 8-13 drawn to a method of prophylaxis of various disorders using a chemical compound of formula I.	Not provided

As indicated above, through this response, Applicants provisionally elect invention Group I ***with traverse***, namely, claims 1-6, 14 and 15 drawn to a chemical compound and a pharmaceutical composition of formula I. Additionally, as requested by the Examiner, Applicants have also provisionally elected with traverse a sub-generic species falling within the scope of invention Group I to be a compound of formula I, wherein $R_1 = R_3 = R_6 = R_7 = R_8$ = hydrogen, $R_2 = R_4$ = halogen, R_5 = alkyl, R_9 = L-G, wherein L = $NR_{30}CO$-, and G = $C_a(OR_{32})_xH_{2a+1-x}$, wherein $R_{30} = R_{32}$ = hydrogen and x = a = 5. A single specific compound falling within this sub-generic species is N-[3-(6,8-dichloro-2-methyl-1,2,3,4-tetrahydroisoquinolin-4-yl)phenyl]-(2R,3S,4R,5R)-2,3,4,5,6-pentahydroxyhexanamide, which is described as Example 2 at line 42, page 43 to line 22, page 44 of the specification. Please note that all of claims 1 to 6, 14 and 15 read on this elected subgeneric species as well as the single disclosed compound as provisionally elected herein. Examiner's imposition of five-way restriction is respectfully traversed below.

Applicants respectfully submit that this four-way restriction as imposed by the Examiner is improper based on the following grounds:

1. There is no undue burden on the Examiner to search for all of the claims as they are believed to be in same or similar classifications.

2. Product, process of making them and their uses should be rejoined pursuant to MPEP 821.04

Now, we address each one of these issues in greater detail. First, Applicants respectfully submit that the search of all of the claims 1 to 15 should not impose any undue burden on the Examiner. In support of our assertion, we draw Examiner's attention to the Table shown above, which lists all groupings of the invention. However, the Examiner has neither provided the search classifications for these invention groups nor she has provided reasoning for any undue burden on the Examiner to search these inventions together. Applicants respectfully submit that such assertions must be provided in the Office Action in support of any imposition of restriction requirement under 35 U.S.C. 121. Nevertheless it is respectfully submitted that all of the four invention groups are believed to be in the same or similar classifications. Thus it is submitted that all invention Groups can be searched together imposing no undue burden on the Examiner. Even more importantly, it should be noted that invention Group I is directed to compounds of formula I, and its pharmaceutical compositions. Whereas, invention Group II is directed to a medicament comprising a compound of Formula I. Further, invention Groups III and IV are directed to either method of treatment or prophylaxis of various disorders using a compound of formula I. Thus it is submitted that when the Examiner is searching for invention Group I, that itself may facilitate the search of invention Groups II to IV. Thus, it should not impose any undue burden on the Examiner to search all inventions together. Therefore, Applicants respectfully submit that all inventions be rejoined and examined together.

Secondly, Applicants submit that product and the related process and use claims should be rejoined pursuant to MPEP 821.04. As noted in MPEP 821.04:

> "However, if *applicant elects claims directed to the product*, and a product claim is subsequently found allowable, *withdrawn process claims* which depend from or otherwise include all the limitations of the allowable product claim *will be rejoined.*

> Where the application as originally filed discloses the product and the *process for making and/or using the product*, and only claims directed to the product are presented for examination, when a product claim is found allowable, applicant may present claims directed to the *process of making and/or using the patentable product by way of amendment pursuant* to **37 CFR 1.121**. (emphasis added)

As already discussed above, invention Group I, claims 1-6, 14 and 15, recites a compound of formula (I), and a pharmaceutical composition thereof. Whereas invention Group II, claim 7, is directed to a medicament comprising compound of formula I. In addition, invention Groups III and IV, claims 8-13, are directed to method of using a compound of formula I of invention Group I in treating or prophylaxis of various disorders. It should especially be noted that claims 7-13 depend directly or indirectly on claim 1 and incorporate all of the limitations of claim 1, i.e., of invention Group I. Thus, it is submitted that all invention Groups II to IV should be rejoined with invention Group I pursuant to provisions set out in MPEP 821.04, as also noted by the Examiner in the outstanding Office Action and in further accordance with the new guidelines established by the Office.

In the event the Examiner wishes to contact the undersigned regarding any matter, please call (collect if necessary) the telephone number listed below.

Applicants believe there are no fees due for this response. However, if the Examiner deems that fees are due, please charge these fees to Deposit Account No. **18-1982** for sanofi-aventis, U.S. LLC, Bridgewater, NJ. Please credit any overpayment to Deposit Account No. **18-1982**.

Respectfully submitted,

June 14, 2006

Balaram Gupta

Balaram Gupta
Registration No. 40,009
Attorney for Applicants

sanofi-aventis U.S. LLC
U.S. Patent Operations
Route #202-206 / P.O. Box 6800
MAIL STOP: BWD-303A
Bridgewater, NJ 08807-0800
Telephone: 908-231-3364
Telefax: 908-231-2626